

Appendix 2: Characteristics of studies included in the systematic review of randomised trials comparing hysterectomy, endometrial ablation and Mirena® for heavy menstrual bleeding

Paper/ Number of women randomised	Patients*	Intervention†	Stated key outcome measures	Patient satisfaction and how it was measured	Individual patient data received?
Hysterectomy vs first generation endometrial destruction					
Dickersin et al 2007 ⁴⁰ ‡ (Design and methods paper also done (Dickersin et al, <i>Control Clin Trials</i> 2003;24:591-609)) Raw data available N = 237	Women with dysfunctional uterine bleeding. Up to 3 fibroids allowed, must each be smaller than 3cm.	Endometrial ablation v hysterectomy	Major problem solved (primary outcome) Resolution of problem Bleeding Pain Fatigue Quality of life Adverse events Re-operation rate Follow-up reported at 12 months, 2 and 5 years; individual patient data at 6 months, 3 and 4 years also received	Women were asked if their major problem was solved from baseline. Answers were given using the following scale: Yes No	Yes
Zupi et al 2003 ¹⁸ Raw data available N = 203	Women with heavy menstrual bleeding. Fibroids excluded.	TCRE v Laparoscopic supracervical hysterectomy	Primary outcome unclear Duration of hospitalisation Period of convalescence Perioperative complications Resumption of usual activities Quality of life Follow-up reported at 3 months, 1 and 2 years	No comparable measure.	Yes
Crosgnani et al 1997 ³⁵ N = 92	Women with heavy menstrual bleeding <50 yrs old with a mobile uterus smaller than a 12 week pregnancy. Fibroids excluded if larger than 3cm.	TCRE v Vaginal hysterectomy	Satisfaction (primary outcome) Improvement in menstrual blood loss Operating time Complications Post-operative hospital stay Resumption of usual activities Resumption of work activities Quality of life Follow-up reported at 2 years	Women were asked how satisfied they were with their operation. Answers were given using the following scale: Very satisfied Satisfied Uncertain Dissatisfied Very dissatisfied	No

O'Connor et al 1997 ³⁸ Raw data available N = 202	Women with symptomatic heavy menstrual bleeding. Fibroids excluded if larger than 5cm.	TCRE v Abdominal + Vaginal hysterectomy	Satisfaction (primary outcome) Need for further surgery Quality of life Duration of surgery Duration of hospital stay Operative and postoperative complications Resumption of work activities Resumption of usual activities Resumption of sexual activities Follow-up reported at 3 months, then 1, 2 and 3 years	Women were asked how satisfied they were with their treatment. Answers were given using the following scale: Very satisfied Satisfied Not sure Dissatisfied Very dissatisfied	Yes
Pinion et al 1994 ³⁹ Raw data available N = 204	Women who would have otherwise had a hysterectomy for heavy menstrual bleeding. Individual patient data showed that fibroids were included; exact eligibility details regarding this parameter not given in paper.	TCRE + Laser v Abdominal hysterectomy	Satisfaction (primary outcome) Operative complications Post-operative recovery Relief of menstrual symptoms Relief of other symptoms Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment. Answers were given using the following scale: Very satisfied Moderately satisfied Dissatisfied Very dissatisfied	Yes
Dwyer et al 1993 ³⁶ (Health economics papers also done (Sculpher et al, <i>Br J Obstet Gynaecol</i> 1996;103:142-9; Sculpher et al, <i>Int J Technol Assess Health Care</i> 1998;14:302-19)) Raw data available N = 200	Women needing surgical treatment for heavy menstrual bleeding. Individual patient data showed that fibroids were included; exact eligibility details regarding this parameter not given in paper.	TCRE v Abdominal hysterectomy	Satisfaction (primary outcome) Post-operative complications Duration of operation Length of hospital stay Resumption of work activities Resumption of usual activities Resumption of sexual activities Changes in premenstrual symptoms Quality of life Need for further surgery Total health service resource cost Follow-up reported at 4 months and 2 years	Women were asked how satisfied they were with their operation. Answers were given using the following scale: Very satisfied Quite satisfied Not very satisfied Dissatisfied	Yes
Gannon et al 1991 ³⁷	Women with heavy	TCRE v Abdominal	Primary outcome unclear	No comparable measure.	Yes

Raw data available N=54	menstrual bleeding. Fibroids excluded.	hysterectomy	Length of operating time Hospitalisation Recovery Cost of surgery Change in menstrual blood loss Post-operative complications Need for further surgery Resource cost of surgery Follow-up reported at 12 months		
Hysterectomy v Mirena®					
Hurskainen et al 2001 ⁴¹ (5yr follow-up study also done (77)) Raw data available N = 236	Women with heavy menstrual bleeding. Fibroids excluded.	Mirena® v Hysterectomy (Abdominally, vaginally or laparoscopically)	Quality of life (EQ-5D) (primary outcome) Quality of life (SF-36) Cost-effectiveness Adverse events General health (VAS) Anxiety/depression Sexual functioning Follow-up reported at 12 months and 5 years; individual patient data at 6 months also received	No comparable measure.	Yes
First vs second generation endometrial destruction					
Brun et al 2006 ³⁴ Raw data available N = 62	Women with heavy menstrual bleeding unresponsive to medical treatment. Submucous fibroids excluded, other fibroids included (further details not given)	TCRE v Thermal balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Satisfaction PBAC (Higham blood loss) score Operative time Discharge time Complication rate Resumption of normal activities Follow-up reported at 6 and 12 months; individual patient data at 3 months also received	Refers to 'satisfaction rate'. Answers were given using the following scale: Excellent Good Moderate Bad	Yes
J Cooper 2004 ⁴⁹ Raw data available N = 322	Women with documented heavy menstrual bleeding due to benign causes. Fibroids excluded if larger	Rollerballv Microwave	Satisfaction Amenorrhoea rate Duration of procedure Anaesthesia	Women were asked how satisfied they were with their treatment. Answers were given using the	Yes

	than 3cm.		Type of anaesthesia Device-related complications Adverse events Dysmenorrhoea Quality of life questionnaire (SF-36) Acceptability of treatment Follow-up reported at 3,6 and 12 months	following scale: Very satisfied Satisfied Dissatisfied	
Perino et al 2004 ⁵⁰ N = 116	Women with abnormal uterine bleeding. Not stated if fibroids were excluded.	TCRE v ELITT	Amenorrhoea rate (primary outcome) Satisfaction Bleeding status Intraoperative complication rate Duration of procedure Pain Further treatment with hysterectomy Follow-up reported at 12 months and 3 years	Refers to 'patient satisfaction'. Answers were given using the following scale: Very satisfied Satisfied Dissatisfied	No
Duleba et al 2003 ⁴⁷ N = 279	Women with heavy menstrual bleeding due to benign causes. Fibroids excluded if larger than 2cm.	Rollerball vEndometrial cryoablation	PBAC (Higham blood loss) score (primary outcome) Satisfaction Bleeding Pain Adverse events Anaesthesia Pre Menstrual Symptoms Follow-up reported at 12 months	Women were asked how satisfied they were with the outcome of the procedure. Answers were given using the following scale: Very Slightly Not at all	No
Hawe et al 2003 ⁴² Raw data available N = 72	Women with dysfunctional uterine bleeding requesting conservative surgical management of their condition. Fibroids excluded.	Nd: Yag Laser v Thermal Balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Satisfaction Effect on blood loss Quality of life Sexual activity Acceptability of procedure Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment. Answers were given using the following scale: Very satisfied Moderately satisfied Dissatisfied Very dissatisfied	Yes
Van Zon-Rabelink et al 2004 ⁴³ (Technical	Women with dysfunctional uterine	Rollerball v Thermal Balloon	PBAC (Higham blood loss) score (primary outcome)	Refers to 'patient satisfaction'.	Yes

safety report also done (Van Zon-Rabelink et al, <i>Eur J Obstet Gynecol Reprod Biol</i> 2003;110:220-3)) Raw data available N = 139	bleeding. Individual patient data showed that fibroids were included; exact eligibility details regarding this parameter not given in paper.		Satisfaction Quality of life Menstrual status Follow-up reported at 6 and 12 months and 2 years	Answers were given using the following scale: Satisfied Not satisfied	
J Cooper et al 2002 ⁴⁸ N = 265	Women with symptomatic heavy menstrual bleeding. Fibroids excluded	Wire loop resection + Rollerball v Bipolar radiofrequency (NovaSure)	PBAC (Higham blood loss) score (primary outcome) Satisfaction Procedure time Sedation Intraoperative complications Postoperative complications Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with the outcome of the procedure. No precise information was given on the scale used to answer this question and individual patient data was not received. Percentage of women very satisfied or satisfied was quoted.	No
Pellicano et al 2002 ⁵³ N = 82	Women with heavy menstrual bleeding unresponsive to medical treatment. Fibroids excluded.	TCRE v Thermal Destruction (Cavaterm)	Satisfaction (primary outcome) Operative time Discharge time Complication rate Re-intervention rate Resumption of normal activities Follow-up reported at 3 and 12 months and 2 years	Women were asked about the improvement of their health state after the procedure Answers were given using the following scale: Excellent Good Moderate No improvement	No
Corson et al 2001 ¹⁹ N = 276	Women with heavy menstrual bleeding due to benign causes. Fibroids excluded if larger than 4cm.	Rollerball v Hydroablator (HTA)	PBAC (Higham blood loss) score (primary outcome) Amenorrhoea rate Adverse events Need for further surgery Operative complications Follow-up reported at 6 and 12 months	No comparable measure.	Yes
Soysal et al 2001 ⁴⁴	Menorrhagic women over	Rollerball v Thermal	PBAC (Higham blood loss) score (primary	Women were asked how satisfied	No

N = 96	40 with a mobile myomatous uterus smaller than 12 week pregnancy. Fibroids excluded if larger than 3cm.	Balloon	outcome) Satisfaction Duration of procedure Complication rates Post-operative pain scores Amenorrhoea rates Follow-up reported at 12 months	they were with their operation. Answers were given using the following scale: Very satisfied Satisfied Dissatisfied	
Corson et al 2000 ⁵² N = 276	Women with heavy menstrual bleeding, without organic uterine disease, who failed or poorly tolerated medical therapy. Fibroids excluded if larger than 2cm.	TCRE + Rollerball v Thermal Balloon (Vesta)	PBAC (Higham blood loss) score (primary outcome) Amenorrhoea Adverse events Quality of life Follow-up reported at 12 months and 2 years	No comparable measure.	No
K Cooper et al 1999 ⁵¹ (2yr follow-up study also done (Bain et al, <i>Obstet Gynecol</i> 2002;99:983-7), 5yr (69) and 10 year (81) follow-up study also) Raw data available N = 263	Women referred for endometrial destruction surgery. Fibroids included; exact eligibility details regarding this parameter not given in paper.	TCRE + Rollerball v Microwave	Satisfaction (primary outcome) Acceptability of treatment Menstrual Status Quality of life Morbidity Duration of procedure Intraoperative complications Postoperative pain relief Postoperative stay. Absence from work Follow-up done reported at 12 months, 2 years, 5 years and 10 years	Women were asked how satisfied they were with their treatment. Answers were given using the following scale: Totally satisfied Generally satisfied Fairly satisfied Fairly dissatisfied Generally dissatisfied Totally dissatisfied	Yes
Meyer et al 1998 ⁴⁶ Raw data available N = 275	Women with heavy menstrual bleeding. Fibroids excluded.	Rollerball v Thermal Balloon (Thermachoice)	PBAC (Higham blood loss) score (primary outcome) Satisfaction Improvement in dysmenorrhoea symptoms Inability to work Complication rate Duration of procedure	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied	Yes

			Requirement for additional surgery Follow-Up done at 3,6 and 12 months	Not satisfied	
Romer et al 1998 ⁴⁵ N = 20	Women with recurrent, therapy refractory heavy menstrual bleeding. Fibroids excluded (Intrauterine abnormalities excluded, so assumed this included fibroids).	Rollerball v Thermal Balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Hypomenorrhoea rate Follow-up reported at 12 months	No comparable measure.	No
Mirena® vs first generation endometrial destruction					
Malak et al 2006 ⁵⁵ N = 60	Women with excessive uterine bleeding. Up to 3 fibroids allowed, must each be smaller than 3cm.	TCRE v Mirena®	Primary outcome unclear PBAC (Higham blood loss) score LNG-IUS discontinuation rate Effect of menstrual bleeding on general well- being, work performance, physical activity and sexual activity assessed using VAS Follow-up reported at 12 months	No comparable measure.	No
Kittelsen et al 1998 ⁵⁶ (Long-term follow-up paper also done (Rauramo et al, <i>Obstet Gynecol</i> 2004;104:1341-21)) N = 60	Women with heavy menstrual bleeding. Fibroids excluded.	TCRE v Mirena®	Primary outcome unclear Quality of life Additional treatments received Adverse events Follow-up reported at 12 months, 2 years and 3 years	No comparable measure.	No
Crosignani et al 1997 ²⁰ N = 70	Women with dysfunctional uterine bleeding. Fibroids excluded.	TCRE v Mirena®	Primary outcome unclear Satisfaction Reduction in menstrual bleeding Health-related quality of life Amenorrhoea rates Additional treatments Adverse events Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied Uncertain Dissatisfied	No
Mirena® v second generation endometrial destruction					
Shaw et al 2007 ⁵⁹	Women with heavy	Thermal Balloon v	PBAC (Higham blood loss) score (primary	Women were asked for their	No

N = 66	menstrual bleeding. Fibroids excluded.	Mirena®	outcome) Satisfaction Continuation with treatment Hysterectomy rates Follow-up reported at 3, 6, 9 and 12 months and 2 years	perception of their treatment effect Answers were given using the following scale: Very good Good Poor	
Tam et al 2006 ⁶⁰ Raw data available N = 44	Women with excessive menstrual bleeding attending the outpatient gynecology clinic. Individual patient data showed that fibroids were included; exact eligibility details regarding this parameter not given in paper.	Thermal Balloon v Mirena®	Primary outcome unclear Health status function SF-36 Follow-up reported at 12 months; individual patient data at 6 months also received	No comparable measure.	Yes
Busfield et al 2005 ⁵⁸ (Cost-effectiveness paper done (70)) Raw data available N = 79	Women with heavy menstrual bleeding. Fibroids excluded if larger than 3cm.	Thermal Balloon v Mirena®	PBAC (Higham blood loss) score (primary outcome) Satisfaction Quality of life Menstrual symptoms Adverse events Treatment failures Follow-up reported at 3, 6 and 12 months, and 2 years	Women were asked if the menstrual symptoms had been successfully treated. Answers were given using the following scale: Definitely yes Probably yes Not sure Probably no Definitely no	Yes
Barrington et al 2003 ²¹ Raw data available N = 50	Women with heavy menstrual bleeding. Fibroids excluded.	Thermal Balloon v Mirena®	Primary outcome unclear PBAC (Higham blood loss) score Amenorrhoea Follow-up reported at 6 months	No comparable measure.	Yes
Soysal et al 2002 ⁵⁷ N = 72	Women with dysfunctional heavy	Thermal Balloon v Mirena®	PBAC (Higham blood loss) score (primary outcome)	Women were asked about their degree of satisfaction	No

	menstrual bleeding. Fibroids excluded if larger than 2cm.		Satisfaction Health-related quality of life Additional treatments Adverse events Follow-up reported at 12 months	recommendation. Answers were given using the following scale: Highly recommends Recommends Did not know Did not recommend	
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*Information about fibroids/ uterine pathology provided in this column to allow assessment of generalisability of the trials.

†TCRE – TransCervical Resection of the Endometrium

‡ELITT – Endometrial Laser Intrauterine Thermal Therapy